

AGENDA

CIRCULATORY SYSTEM DEVICES PANEL

June 20, 2000

Gaithersburg Hilton

620 Perry Parkway, Gaithersburg, Maryland

8:00 – 10:00 a.m.	Closed Session	FDA and Panel Personnel Only
10:00 a.m.	Call to Order	Anne B. Curtis, M.D. Chairperson
	Conflict of Interest Statement	Megan Moynahan Executive Secretary
	Open Public Hearing*	
10:30 a.m.	Open Committee Discussion	Anne B. Curtis, M.D. Chairperson
	The committee will discuss a modification to the guidance document titled, "DRAFT Guidance for Implantable Cardioverter-Defibrillators", concerning indications for use for these devices.	
	FDA Presentation	
	Panel Discussion	
12 noon	Lunch	
1:00 p.m.	Resume Open Committee Discussion	Anne B. Curtis, M.D. Chairperson
2:30 – 2:45 p.m.	Break	
	Open Public Hearing**	
4:00 p.m.	Adjourn	

10:00 - 10:30 a.m. OPEN PUBLIC HEARING*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Moynahan will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Curtis will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.

Scheduled Speakers are given a ten minute limit.

<u>Name</u>	<u>Affiliation</u>
Dr. John Fisher, M.D.	Albert Einstein College of Medicine, Medtronic
Dr. Marshall S. Stanton, M.D.	Medtronic, Inc.

Unscheduled speakers may have time designated by the Chair.

OPEN PUBLIC HEARING**

Near the end of the committee deliberations, on each specific device being discussed, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee.